

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH	)	
BENEFITS FUNDS, PIRELLIARMSTRONG	)	CIVIL ACTION NO. 1:05-CV-11148-PBS
RETIREE MEDICAL BENEFITS TRUST,	)	
TEAMSTERES HEALTH & WELFARE	)	Judge Patti B. Saris
FUND OF PHILADELPHIA AND VICINITY,	)	
PHILDELPHIA FEDERATION OF	)	
TEACHERS HEALTH AND WELFARE	)	
FUND, DISTRICT COUNCIL 37, AFSCME –	)	
HEALTH & SECURITY PLAN; JUNE SWAN; )		
MAUREEN COWIE AND BERNARD	)	
GORTER,	)	
Plaintiffs,	)	
v.	)	
	)	
FIRST DATABANK, INC., a Missouri	)	
corporation , and McKESSON	)	
CORPORATION, a Delaware corporation,	)	

Defendants.

**REBUTTAL REPORT OF DR. KIMBERLY P. MCDONOUGH**

I am submitting this rebuttal report to address claims made by Defendant's expert Dr. Willig in Appendix 2 of his supplemental report, titled *Comments on Various Claims in the McDonough Report*. Although Dr. Willig says that he has not chosen to respond to all aspects of my report, I, of course, can only respond to the points that he has offered at this point.

**I. PBM contracting**

Dr. Willig alleges that my claims about the prevalence of three year contracts between PBMs and TPPs are unsubstantiated. He indicates that of the twelve contracts submitted in this case, only five were written for a period of three years.<sup>1</sup>. Dr. Willig

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<sup>1</sup> It is interesting to note that in his review of the same twelve contracts, Mr. Flum, an attorney of record for McKesson, indicates that six of these contracts were issued for a term of three years. Declaration of Paul Flum in Support of McKesson Corporation's

further indicates that my citation of the CalPERS contract is insufficient evidence of the prevalence of three-year contracts. These comments are misleading because they ignore the full basis for my expert opinion on this subject.

My testimony regarding the duration of PBM contracts is based on my ten years of consulting experience, my previous experience working in the PBM industry and my review of contracts and proposed contract terms through the services I provide to my clients. My clients include MCOs, Blues plans, Fortune 1000 companies and other PBM consultants. In the course of negotiating contracts or evaluating pharmacy benefit services for my clients, I have reviewed over 100 contracts between PBMs and TPPs. I have reviewed contracts from each of the 3 major PBMs.

Mr. Willing suggests that clients should have renegotiated contract terms during the middle of their contract to compensate for the increases in AWP prices resulting from the change in AWP to WAC ratio. However, Dr. Willig ignores the reality of contracting within the PBM industry. To effect a change during the term of the contract, both parties would have to agree to open these negotiations. Although renegotiation of contract terms might have been beneficial to the TPP, there was no financial incentive for a PBM to open contract negotiations, particularly, as discussed in my initial report, if the PBM was generating higher profit margins through pharmacy network spreads and in its mail pharmacy operations.

It is also important to understand the amount of time necessary for a TPP to renegotiate or to change PBMs. To change PBMs, and often to renegotiate a PBM contract, a TPP will issue written Request for Proposals (RFPs) and encourage several PBMs to make proposals. It commonly takes four to six months to draft and issue RFPs, evaluate the responses and choose the best candidate among the responding PBMs. It would then take several more months for a TPP to convert to a new PBM. Thus, a TPP that desired better contract rates would still need a year to search for, locate, negotiate with and change over to a new PBM.

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response to Dr. Hartman's September 14, 2007 Submission Regarding the Court's Class Certification Order.

Dr. Willig claims that, although I have discussed the unlikelihood that a TPP would be permitted to terminate its PBM contract, I have not discussed whether a TPP could renegotiate its PBM contract. I have worked with a few clients for whom the contract was renegotiated during the term of the contract. In each case, the renegotiation was the result of an RFP evaluation process in which the incumbent PBM accelerated the terms contract in an effort to retain the client and terminate the RFP process. Thus, the analysis of how difficult it would be for a TPP to renegotiate a PBM contract is similar to the analysis of how difficult it would be to terminate one.

I saw no increase in the number of TPPs wanting to renegotiate or change PBMs during 2002 or 2003. At most TPPs, internal resources for contracting are limited and prioritized in coordination with strategic initiatives for each year. As a matter of practical items, most TPPs were working on HIPAA compliance in 2002 and 2003 and resources for other pharmacy initiatives were not often available.

However I have recently seen an example of a PBM wishing to renegotiate its contracts with TPPs. Express Scripts ("ESI") has been requesting a contract revision to preserve the relative economic relationship of the parties in the event of a change in the methodology used to determine AWP. ESI will seek to reduce TPPs' AWP discounts to maintain the same spread and profit levels as currently exist. ESI is saying it will seek to do this even though ESI certainly did not offer to increase AWP discount levels in 2002 when the AWP bump-up occurred.

This shows that PBMs can correct for a change in AWP/WAC spread when they have the motivation to do so. After the AWP to WAC increases in 2002, they did not seek to do so.

In response to this contract revision request by ESI, several of my clients have requested an evaluation of the relative value of AWP to WAC, both currently and in 2001, prior to the change in AWP to WAC ratio. Because my staff has access to First Databank pricing files dating to 1997, we are able to conduct this assessment. By using the NDC-level drug indicators, my staff is able to compare the current AWP to WAC ratio for drugs expenditures to the AWP to WAC ratios for these same drugs in 2001. By doing so we are able to determine if the AWP discounts currently offered by the PBM

sufficiently offset the AWP price increases incurred as a result of the change in AWP to WAC ratio at issue in this case.

II. TPPs' ability to recoup increased costs due to the change in AWP methodology

Mr. Willing suggests that TPPs are able to use formularies, tiered copays, and utilization controls to completely offset the increased AWP costs incurred as a result in the change in AWP to WAC ratio. This position is naïve and is contradicted by what I have seen in over 17 years in the managed care industry. If a TPP were able to unilaterally adjust contract terms to compensate for price increases, pharmacy benefit cost inflation would have been non-existent for the past 17 years. This is certainly not the case.

Dr. Willig suggests that the AWP price increases could have been completely offset by the drug management tools indicated above. In fact, while drug management tools help to slow the trend of inflation in pharmacy benefits, they do not completely offset this trend. For example, a TPP could have theoretically raised the copay of Neurontin and Lipitor in response to the AWP changes that occurred in 2002. However, doing so would have resulted in a loss of rebate payments for all Pfizer products. In the case of a health plan, the change in benefit would also likely require approval by the Department of Insurance in each state where the health plan provides benefits. In the case of a collectively bargained benefit, changes would not be possible during the contract term. Formularies and utilization controls are subject to similar administrative limitations. These real life limitations would have substantially restricted any TPP in efforts to offset the price increases that resulted from the change in AWP to WAC ratio.

Similarly, Dr. Willig indicates that the lack of change in the rate of AWP price reported by PBMI ignores potential changes in rebates that could offset the AWP price increases. First, Dr. Willig ignores that most TPPs don't negotiate rebates, but rely on their PBM to negotiate manufacturer rebate contracts of the TPPs' behalf. These rebate contracts are proprietary to the PBM and the terms are not known to the TPP. Rebates are earned by virtue of a product's preferred placement on the PBM's or TPP's formulary. Therefore, rebates can only be earned on drugs placed on formulary.

Most importantly, rebates are typically paid based on WAC, not AWP. The reason for this is quite simple: manufacturers want to pay rebates based on their list prices rather than inflated AWPs.

Under the provisions of the Omnibus Reconciliation Act of 1990 (OBRA90), manufacturers must report to CMS the value of rebates and other price concessions given to the private sector. If manufacturers provide rebates to a TPP or PBM that exceed the federally-mandated Medicaid rebate, the manufacturer must extend these same, higher rebates to Medicaid under the "best price" provisions of the OBRA90. As a practical matter, few manufacturers are willing to supply rebates that exceed the mandated Medicaid rebate.

Dr. Willig also suggests that changes in dispensing fees paid to pharmacies could also have offset the impact of AWP increases. Dr. Willig ignores that this proposed offset doesn't work as a matter of math. In my experience, PBM contracts offer retail pharmacy dispensing fees that rarely exceed \$2.00 per prescription, while PBMs offer mail pharmacy services with no dispensing fee. In contrast, a 5% increase in a month's supply of Lipitor would exceed \$5.00 per prescription. Given the financial reality, a change in dispensing fee could not offset the AWP price increases incurred as a result in the change in AWP to WAC ration that occurred in 2002.

Dr. Willig's argument assumes that PBMs always act solely in the best interests of their TPP clients. While it is true that TPPs often rely on PBMs to negotiate aggressive contracts with retail pharmacies on their behalf, in reality, because PBMs use pharmacy payment margins, or spread, as a source of income, they are not necessarily motivated to modify client contracts to compensate for the AWP price changes that resulted from an increase in the AWP-to-WAC ratio.

In addition, all major PBMs own mail order facilities that are compensated by TPPs based on AWPs. These facilities are major sources of revenue for PBMs and are significantly more profitable than the PBM's claims processing-related services. In its 2003 annual report, Medco indicates that 15% of the prescriptions processed by Medco originated from its mail order facilities, accounting for \$11.3 billion in revenue for that

year alone. Express Scripts likewise filled over 39.1 million prescriptions through its mail order facility in 2004, almost 10% of its processed prescriptions.

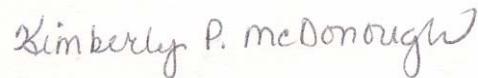
### III. Availability of pass-through contracts

In my report, I indicate that very few PBMs are willing to provide pass-through contracts to their clients. Dr. Willig contends that my testimony in this case differs from my textbook chapter in which I indicate "a new generation of PBM has emerged in the market place" which offers pass-through contracting. What Dr. Willig fails to recognize is the change in the PBM market between the time of the AWP pricing methodology change at issue in this case, and the publication of this textbook. In fact, the emergence of these new PBMs is an industry response to litigation against the PBM industry regarding undisclosed revenues.

Despite the presence of these new PBMs in the marketplace, pharmacy network spread continues to be commonplace. In fact, due to the continuing and widespread use of pharmacy network spread in contracts between PBMs and Plan Sponsors, the Centers for Medicare Services recently revised the methodology required for the submission of pharmacy costs incurred by Medicare Part D plans and under the rules of the Retiree Drug Subsidy payments to address the issue of spread.<sup>2</sup>

I declare under penalty of perjury that the foregoing information is true and correct to the best of my knowledge.

Executed on this 29th day of October, 2007.



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Kimberly P. McDonough, Pharm. D.

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<sup>2</sup> 2008 Part D Payment Notification, CMS Memo, April 2, 2007, page 5.

**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party through the Court's electronic filing service on October 29, 2007.

/s/ Steve W. Berman

Steve W. Berman